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CLAIM OF PRIORITY

[0001] This application claims priority to U.S. Provisional Application No. 60/472,817, filed May 22, 2003, entitled "Cervical Interspinous Process Distraction Implant and Method of Implantation" (Attorney Docket No. KLYC-01087US0).

FIELD OF THE INVENTION

[0002] This invention relates to a cervical interspinous process implant.

BACKGROUND OF THE INVENTION

[0003] The spinal column is a bio-mechanical structure composed primarily of ligaments, muscles, vertebrae and intervertebral disks. The bio-mechanical functions of the spine include: (1) support of the body, which involves the transfer of the weight and the bending movements of the head, trunk and arms to the pelvis and legs, (2) complex physiological motion between these parts, and (3) protection of the

spinal cord and the nerve roots.

[0004] As the present society ages, it is anticipated that there will be an increase in adverse spinal conditions which are characteristic of older people. By way of example only, with aging comes an increase in spinal stenosis (including, but not limited to, central canal and lateral stenosis), and facet arthropathy. Spinal stenosis results in a reduction foraminal area (*i.e.*, the available space for the passage of nerves and blood vessels) which compresses the cervical nerve roots and causes radicular pain. Humpreys, S.C. *et al.*, *Flexion and traction effect on C5-C6 foraminal space*, Arch. Phys. Med. Rehabil., vol. 79 at 1105 (Sept. 1998). Another symptom of spinal stenosis is myelopathy, which results in neck pain and muscle weakness. *Id.* Extension and ipsilateral rotation of the neck further reduces the foraminal area and contributes to pain, nerve root compression and neural injury. *Id.*; Yoo, J.U. *et al.*, *Effect of cervical spine motion on the neuroforaminal dimensions of human cervical spine*, Spine, vol. 17 at 1131 (Nov. 10, 1992). In contrast, neck flexion increases the foraminal area. Humpreys, S.C. *et al.*, at 1105.

[0005] Pain associated with stenosis can be relieved by medication and/or surgery. It is desirable to eliminate the need for major surgery for all individuals, and in particular, for the elderly.

[0006] Accordingly, a need exists to develop spine implants that alleviate pain caused by spinal stenosis and other such conditions caused by damage to, or degeneration of, the cervical spine. Such implants would distract, or increase the space between, the vertebrae to increase the foraminal area and reduce pressure on the nerves and blood vessels of the cervical spine.

[0007] A further need exists for development of a minimally invasive surgical implantation method for cervical spine implants that preserves the physiology of the spine.

[0008] Further, a need exists for an implant that accommodates the distinct anatomical structures of the spine, minimizes further trauma to the spine, and obviates the need for invasive methods of surgical implantation. Additionally, a need exists to address adverse spinal conditions that are exacerbated by spinal extension.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] **FIGS. 1 and 2. Fig. 1** provides a perspective view of an embodiment of an implant of the present invention having a spacer, a distraction guide, and a wing with a cross-sectional elliptical shape. The spacer has a teardrop shape in cross-section perpendicular to its longitudinal axis. **Fig. 2** is an end view of the embodiment of the invention in **Fig. 1**.

[0010] **FIGS. 3 and 4. Fig. 3** is a perspective view of another embodiment of the invention having a wing that is teardrop-shaped in cross-section substantially perpendicular to the longitudinal axis of the spacer. **Fig. 4** is an end view of a second wing for the embodiment of the invention of **Fig. 3**.

[0011] **FIGS. 5, 6, and 7. Fig. 5** is a perspective view of an embodiment of the invention having a rotatable spacer and a wing that is elliptical in cross-section. **Fig. 6** is a perspective view of an embodiment of the invention having a rotatable spacer with two wings that are teardrop-shaped in cross-section. The second wing becomes connected with the spacer after the distraction guide, spacer, and wing are positioned in the cervical spine during surgery. **Fig. 7** depicts the axis of rotation as seen from an end view of the embodiment of the invention of **Fig. 6**.

[0012] **FIGS. 8, 9A, and 9B. Fig. 8** is a perspective view of an embodiment of the invention with a wing that is truncated at its posterior end. **Fig. 9A** is an end view of an embodiment of the invention with

a wing truncated at its posterior end, with a rotatable spacer. **Fig. 9B** is a truncated second wing for the two-winged version of the embodiment of the invention of **Fig. 9A**.

[0013] **FIGS. 10, 11 and 12. Fig. 10** is a plan view of an embodiment of the invention where a screw is used to secure a second wing to the spacer. **Fig. 11** shows a perspective view of the second wing of this embodiment of the invention. **Fig. 12** shows a perspective view of this embodiment of the invention.

[0014] **FIGS. 13A, 13B, 14A and 14B. Fig. 13A** is a side view of an embodiment of a second wing of the invention, depicting a flexible hinge mechanism for securing the second wing to the implant during surgery. **Fig. 13B** is a side-sectional view of the second wing of **Fig. 13A** through line **13B-13B**. **Fig. 14A** is a plan view of the first wing, spacer, and distraction guide depicting the indentation in the spacer that fits with the hinge of the second wing of the embodiment of **Figs. 13A** and **13B**. **Fig. 14B** is a front view of the second wing with flexible hinge of the embodiment of **Figs. 13A** and **13B**.

[0015] **FIGS. 15A, 15B, and 16. Fig. 15A** is a top view of the an embodiment of the invention of **Fig. 3**, positioned between the spinous processes of adjacent cervical vertebrae, which embodiment has wings with anterior ends directed away from the center of the spacer, and truncated posterior ends. **Fig. 15B** is a top view of the implant of **Fig. 15A**. **Fig. 16** is a top view of two such implants of the invention as seen in **Fig. 15**, positioned in the cervical spine.

[0016] **FIG. 17** is a side view of two implants of the invention positioned in the cervical spine, with stops or keeps at the distal ends of the spinous processes.

[0017] **FIG. 18** depicts a method of the invention for surgically implanting an embodiment of the

implant of the invention adjacent to cervical spinous processes of a patient.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS OF THE INVENTION

[0018] The embodiment of the invention includes a cervical spine implant for alleviating discomfort associated with the cervical spine without damage to the bones or other anatomical structures associated with the spine. The embodiment also encompasses a method for minimally invasive surgical implantation.

[0019] An embodiment of cervical spine implant of the invention taught herein is adapted specifically to accommodate the anatomy of the cervical spine and to distract the vertebrae to increase the foraminal area and relieve pressure on the nerve roots. This embodiment of the implant is shaped with smooth, broad sides so that, when it is positioned during surgical implantation between the spinous processes of adjacent cervical vertebrae, the implant distributes the forces acting on it from the bones of the cervical spine. Thus positioned, the implant distracts the cervical spine to alleviate the pressure and restrictions on blood vessels and nerves affected by stenosis and other spinal conditions.

[0020] The embodiment of the invention further discloses a method for minimally invasive surgical implantation. The method for implantation taught herein accommodates structures associated with the cervical spine, and minimizes the need for invasive surgery. As only one example, it is of obvious importance to avoid surgical injury to the *ligamentum nuchae* (supraspinous ligament)in the dorsal neck, a structure which cushions the spinous processes of the upper cervical vertebrae.

[0021] While the cervical spine implant and method for relieving pain address the needs of the

elderly for relief of symptoms of stenosis and the like, the embodiment of the invention also can be used with individuals of all ages and sizes where distraction of the spinous processes would be beneficial.

[0022] The implant is characterized in one embodiment as including a distraction guide, a spacer, and a wing. The distraction guide extends from one end of the spacer and is shaped so that it can distract the spinous processes of adjacent cervical vertebrae so that the spacer then can be urged into place between the spinous processes. A single lateral retaining unit called a wing prevents lateral displacement and rejection of the implant. The wing either extends from or is attached to the spacer.

[0023] In another embodiment of the invention, the implant includes a first unit having a spacer with a distraction guide and a first wing. The embodiment further includes a second wing which fits over the distraction guide to connect with the spacer, and a means for securing the second wing to the spacer. The two wings prevent lateral displacement and rejection of the implant.

[0024] In a further embodiment of the present invention, the implant includes a spacer that is rotatable relative to the wing of the implant. The spacer, which is tear-dropped shaped in cross-section, is received over the shaft of the implant and can rotate thereon about the shaft. It is to be understood that the spacer need not be teardrop-shaped in cross-section; rather, other forms are possible, including but not limited to cylindrical, ovoid, elliptical, and the like.

[0025] It is to be understood that the cortical bone of the spinous processes is stronger at an anterior position, near the vertebral bodies of the vertebra, than at a posterior position distally located from the vertebral bodies. The advantage to using a rotatable spacer is that the rotation allows the surgeon more easily to position the implant anteriorly between spinous processes of adjacent cervical vertebrae.

[0026] An additional feature of the implant is its flat surfaces for load bearing. The flat surfaces in contact with the bone distribute the forces that bear on the bones and the implant because of the distraction.

[0027] As may be required for securing the lateral position of the implant between the spinous processes, a second wing can be connected with the spacer on the end of the spacer that joins with the distraction guide. To connect the second wing, the second wing passes over the distraction guide and is received by the spacer. A fastener is used to secure the second wing to the spacer.

[0028] In yet another embodiment of the implant, the wing or wings have truncated posterior ends to avoid or minimize interaction of the implants and interference with neck rotation. For example, an implant with extended posterior wings, positioned between cervical vertebrae five and six, and a similar implant, placed between cervical vertebrae six and seven, might interfere with each other at the posterior ends of the wings during cervical rotation, depending on the dimensions of a particular patient's vertebrae and surrounding structures. Truncating the posterior ends of the wings can avoid the undesirable consequences of two implants' interaction.

[0029] In a further embodiment of the present invention, the anterior portions of the first and second wings flare outward at an angle from the spacer and away from the anterior ends of each other, in order to accommodate the wedge shape of spinous processes of the certain cervical vertebrae of the cervical spine.

[0030] In another embodiment, stops or keeps are placed around the posterior ends of the spinous processes of adjacent cervical vertebrae between which the implant of any of the above described

embodiments is positioned. The keeps prevent backward displacement of the implant. The keeps can be made of a biocompatible, flexible polymer. Additionally, the keeps can be made of stainless steel, titanium, or a shape memory material such as Nitinol.

[0031] It is to be understood that the distraction guide, spacer, and wings can be of various shapes. For example, the distraction guide can be wedge-shaped or any other shape that introduces distraction between spinous processes of adjacent cervical vertebrae. The spacers, too, can have alternative shapes, defined by their cross sections as teardrop, elliptical, ovoid, etc., which would provide smooth edges and a flat and smooth contact surface area between the spinous processes and the spacer to distribute the forces placed thereon by the bone. The wings also might be teardrop-shaped, elliptical, ovoid, etc., in cross-section, or any other shape that provides smooth flat surfaces and rounded edges.

[0032] In yet another aspect of the invention, a method is presented for relieving pain due to the development of, by way of example only, stenosis and facet arthropathy of the cervical spine. The method is comprised of the steps of accessing the spinous processes of adjacent cervical vertebrae and implanting a cervical spinal distraction device in order to achieve the desired distraction and to maintain that distraction.

[0033] One aspect of the method taught is the use of a guide wire through the neck to guide the positioning of the implant while monitoring the implantation via x-ray.

[0034] Other aspects, objects, features and elements of embodiments of the invention are described or evident from the accompanying specification, claims and figures.

[0035] The following description is presented to enable any person skilled in the art to make and

use the invention. Various modifications to the embodiments described will be readily apparent to those skilled in the art, and the principles defined herein can be applied to other embodiments and applications without departing from the spirit and scope of the present invention as defined by the appended claims. Thus, the present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein. To the extent necessary to achieve a complete understanding of the invention disclosed, the specification and drawings of all patents and patent applications cited in this application are incorporated herein by reference.

[0036] An embodiment of an implant ***100*** of the invention is depicted in **Figs. 1 and 2**. This implant ***100*** includes a wing ***130***, a spacer ***120***, and a lead-in tissue expander, or a distraction guide ***110***. The distraction guide ***110*** in this particular embodiment is wedge-shaped, *i.e.*, has an expanding cross-section from the end distal ***140*** to the region ***150*** where the guide ***110*** joins with the spacer ***120***. As such, the distraction guide functions to initiate distraction of the soft tissue and the spinous processes when the implant ***100*** is surgically inserted between the spinous processes. It is to be understood that the distraction guide can be pointed and the like, in order to facilitate insertion of the implant between the spinous processes of adjacent cervical vertebrae. It is advantageous that the insertion technique disturb as little of the bone and surrounding tissue or ligaments as possible in order to (1) reduce trauma to the site and promote early healing; and (2) prevent destabilization of the normal anatomy. It is to be noted that with the present embodiment, and all of the embodiments herein, there is no requirement to remove any of the bone of the spinous processes and no requirement to remove or sever ligaments and tissues immediately associated with the spinous processes. Specifically, it is unnecessary to remove or sever the *ligamentum*

nuchae, (supraspinous ligament) which partially cushions the spinous processes of the upper cervical vertebrae.

[0037] Additionally, as depicted in **Figs. 1 and 2**, the wing ***130*** in this embodiment ***100*** is elliptically-shaped in a cross-section perpendicular to the longitudinal axis ***125*** of the spacer and distraction guide. As illustrated in the embodiment of **Fig. 3**, and as discussed in more detail herein, the wing ***130*** can have alternative shapes in cross-section, such as teardrop, wedge, circular, oval, ovoid, football-shaped, and rectangular-shaped with rounded corners and other shapes, and be within the spirit and scope of the invention. The wing ***130*** has an anterior portion ***133*** and a posterior portion ***135***.

[0038] Further, as also can be seen in **Figs. 1, 2, and 3** and other embodiments to be discussed herein, the spacer ***120*** is teardrop-shaped in cross-section perpendicular to the spacer's longitudinal axis ***125***. The spacer ***120***, like the wing ***130***, can have alternative shapes such as circular, wedge, oval, ovoid, football-shaped, and rectangular-shaped with rounded corners and other shapes, and be within the spirit and scope of the invention. The shape of the spacer selected for a particular patient should accommodate the wedge-like space between adjacent cervical spinous processes and thus allow the surgeon to position the implant as close as possible anteriorly, near the vertebral bodies.

[0039] It should be appreciated that the shape selected for the spacer ***120*** should create a smooth, flat and relatively broad contact area between the implant ***100*** and the spinous processes of the vertebrae that are to be subject to distraction. Increasing the contact surface area between the implant and the spinous processes distributes the force and load between the spinous frame and the implant. Generally, a teardrop or wedge-shaped spacer allows for more load-bearing contact between the spacer and the

spinous process.

[0040] It is to be understood also that the implant ***100*** can have two wings, with a second wing ***160*** (**Fig. 4**) separate from the distraction guide ***110***, spacer ***120*** and first wing ***130***. The second wing can be connected to the end of the spacer ***120*** distal from the first wing ***130***. It should be noted that the second wing ***160***, like the first wing ***130***, can prevent lateral displacement of the implant ***100*** relative to an individual patient's cervical spine anatomy. In **Fig. 4**, the second wing ***160*** is teardrop-shaped and wedge-shaped in cross-section. The wider section or end ***162*** of the teardrop shape is the posterior end of the second wing ***160*** and the narrower section or end ***169*** is the anterior end of the second wing ***160***. Unlike the first wing ***130***, however, the sides of the second wing ***160*** define a space ***170*** with a lip ***180*** that allows the second wing ***160*** to pass over the distraction guide ***110*** to meet and connect with the spacer ***120***. The second wing ***160*** is then secured to the spacer ***120*** toward the end of the spacer located distally from the first wing ***140***. The second wing ***160*** is implanted once the distraction guide ***110***, spacer ***120***, and first wing ***130*** are inserted as a unit between the spinous processes of adjacent cervical vertebrae.

[0041] It is to be understood that the implant is preferably made in two pieces. The first piece includes the first wing ***130***, the spacer ***120***, and the distraction guide ***110***. The second piece includes the second wing ***160***. Each piece can be made in a number of ways known in the art including by machining and molding. Each piece, as will be more fully discussed can be made of any material that is bio-compatible with the body of a patient. For example the implants can be made of stainless steel and titanium. Additionally, a shape memory metal such as Nitinol, which is a combination of titanium and nickel, can also be used. Further polymers such as described later can also be used. It is further to be understood

that the implant can be formed with multiple pieces and with the pieces appropriately joined together. Further the implant can be formed as one piece or joined together as one piece and be within the spirit and scope of the invention, but without some of the advantages of the embodiment of the invention as exist with a two piece embodiment as shown in **Figs. 1 ,2, 3, and 4**.

[0042] A further embodiment ***200*** of the invention is depicted in **Figs. 5 and 6.** In this embodiment ***200***, the spacer ***210*** is rotatable about its longitudinal axis ***240***, **Fig. 7** relative to a first wing ***130*** (**Fig. 5**), or relative to two wings with respect to an alternative embodiment of the invention (**Fig. 6**). The spacer may also be rotatable or fixed, relative to the distraction guide ***110***. The spacer ***210*** has a bore ***220*** running the length of its longitudinal axis ***240***, with holes at both ends of the spacer ***210***, and a shaft ***230*** inserted through the bore ***220*** and connecting with the distraction guide ***110*** and first wing ***130***. As discussed above, it may be advantageous to position any of the implants taught herein as close as possible to the vertebral bodies. The rotatable spacer ***210*** can accommodate the bone structures of the cervical spine as the implant is inserted between the spinous processes as it follows the distraction guide laterally into position. Spacer rotation accommodates the anatomy of the spinous processes relative to the wings of the implant. Thus, the rotatable spacer ***210*** improves the positioning of the spacer independent of the wings relative to the spinous processes. The embodiment of **Fig. 6** has a first wing ***130*** and if desired, a second wing ***160*** similar to the wing depicted in the embodiment of **Fig. 3**. As will be discussed below, the shape of the wings in **Figs. 3 and 6** is such that the implants accommodate the twisting of the cervical spine along its axis as, for example, the head of a patient turning from side to side.

[0043] **FIGS. 8, 9A, and 9B** show a perspective view (**Fig. 8**) and an end view (**Fig. 9A**) of

another embodiment ***300*** of the invention, wherein the posterior portion ***135*** of the teardrop-shaped first wing ***130*** is truncated at end ***310***, making the first wing ***130*** more ovoid. In this configuration, the anterior portion ***133*** of the first wing ***130*** is longer than the truncated posterior end ***310*** of the first wing ***130***. The embodiment ***300*** can also have a rotatable spacer ***210***. It should be appreciated, as illustrated in **Fig. 9B**, that the second wing in a two-winged version of this embodiment of the invention ***300***, would be a truncated second wing ***350*** with a truncated posterior end ***340***.

[0044] The purpose of embodiment ***300***, as with the other embodiments, is to minimize the possibility of interference of implants positioned between the spinous processes of adjacent pairs of cervical vertebrae, *e.g.*, implants between cervical vertebrae five and six, and between six and seven. During rotation of the neck, the spinous process move past each other in a scissor-like motion. Each cervical vertebra can rotate relative to the next adjacent cervical vertebra in the general range of about 6°-12°. It is to be understood that in addition, about 50 percent of the rotational movement of the neck is accomplished by the top two neck vertebrae. Thus, such embodiments can accommodate neck rotation without adjacent embodiments interfering with each other.

[0045] With respect to the prior embodiments which have first and second wings, the second wing ***160***, **Fig. 4** can be designed to be interference-fit onto the spacer ***120*** or, in the case of a rotatable spacer ***210***, **Fig. 5**, a portion of the end of the distraction guide ***110*** adjacent to the spacer ***120***. The spacer ***120*** is associated with the first wing ***130***. Thus, there is no additional attachment device to fasten the second wing ***160*** relative to the remainder of the implant. However, as described below and as desired, various fasteners can be used to secure the second wing ***160*** relative to the remainder of the implant.

[0046] **FIGS 10, 11, and 12** depict an embodiment ***400*** with a teardrop-shaped second wing ***410*** that has a bore ***420*** through a tongue ***430*** at the posterior end of the second wing ***160***. The bore on the second wing ***420*** is brought into alignment with a corresponding bore ***440*** on the spacer ***120*** when the second wing ***160*** is brought into position by surgical insertion relative to the rest of the implant. A threaded screw ***450*** is inserted through the aligned bores in a posterior-anterior direction to secure the second wing ***160*** to the spacer ***120***. The direction of insertion from a posterior to an anterior direction has the screw engaging the bores and the rest of the implant along a direction that is generally perpendicular to the longitudinal axis of the spacer ***125*** (**Figs. 1 and 3**). This orientation is most convenient when the surgeon is required to use screw ***450*** to secure the second wing ***160*** to the rest of the implant. Other securing mechanisms using a member inserted into corresponding bores ***420, 440*** on the spacer ***120*** and second wing ***160*** are within the spirit of the invention. It should be understood that a rotatable spacer ***210*** also can be accommodated by this embodiment. With a rotatable spacer ***210***, the second wing ***160*** would be attached to the end of the distraction guide ***110*** that is located adjacent to ***150*** the rotatable spacer ***210***.

[0047] **FIGS. 13A, 13B, 14A, and 14B** depict a further embodiment ***500*** wherein the second wing ***160*** is secured to the spacer ***120*** by a mechanism including a flexible hinge ***515***, with a protrusion ***530*** on the end of the hinge ***510*** adjacent to the lip ***180*** of the hole ***170*** defined by portions of the second wing ***160***. The securing mechanism also encompasses an indentation ***540*** on the spacer ***120***, wherein the indentation accommodates the protrusion ***530*** on the end of the flexible hinge ***515***. During surgery, after insertion of the distraction guide ***110***, spacer ***120***, and first wing ***130***, the second wing ***160*** is received over

the distraction guide ***110*** and the spacer ***120***. As the second wing ***160*** is received by the spacer ***120***, the flexible hinge ***515*** and its protrusion ***530*** deflect until the protrusion ***530*** meets and joins with the indentation ***540*** in the spacer ***120***, securing the second wing ***160*** to the spacer ***120***. Again in embodiments where the spacer can rotate, the indentation ***540*** is located on an end of the distraction guide ***110*** that is adjacent to ***150*** the rotatable spacer ***210***. With respect to the flexible hinge ***515***, this hinge is in a preferred embodiment formed with the second wing ***160*** and designed in such a way that it can flex as the hinge ***515*** is urged over the distraction guide ***110*** and the spacer ***120*** and then allow the protrusion ***530*** to be deposited into the indentation ***540***. Alternatively, it can be appreciated that the indentation ***540*** can exist in the second wing ***160*** and the flexible hinge ***515*** and the protrusion ***530*** can exist on the spacer ***120*** in order to mate the second wing ***160*** to the spacer ***120***. Still alternatively, the flexible hinge ***515*** can be replaced with a flexible protrusion that can be flexed into engagement with the indentation ***540*** in the embodiment with the indentation ***540*** in the spacer ***120*** or in the embodiment with the indentation ***540*** in the second wing ***160***.

[0048] **FIGS. 15A, 15B, and 16.** These figures illustrate an embodiment ***600*** wherein the first wing ***130*** and second wing ***160*** flare out at an angle away from the spacer ***120*** and away from each other. That is the anterior ends of the first and second wings flare away from each other. The cervical spinous processes are themselves wedge-shaped when seen from a top view. Accordingly, it is advantageous that the implant ***600*** accommodate this wedge shape so that the implant ***600*** can be positioned as close as possible to the vertebral bodies of the spine where the load of the spine is carried. Thus the first ***130*** and the second wings ***160*** are positioned relative to the spacer, whether the spacer is fixed ***120*** or rotatable

210, so that the wings flare out as the wings approach the vertebral body of the spine. **Figure 15B** depicts a top view of the implant *600* of **Fig. 15A**. As is evident from **Fig. 15B**, the first wing *130* is formed at an angle with respect to a line that is perpendicular to the spacer *120*. In a preferred embodiment, the angle is about 30°, with a preferable range *θ* from about 15° to about 45°. Other angles of the first wing *130* relative to the spacer *120* are contemplated and in accordance with the invention. The second wing *160* is also preferably provided at an angle of about 30° relative to a line that is perpendicular to the spacer with a preferable range *θ* from about 15° to about 45°. In other words, the wings form an obtuse angle with respect to the spacer *120* in this embodiment. The second wing *160* defines an inner hole *170* which is outlined by the lip *180*. As is evident, the lip *180* is provided at an angle relative to the rest of the second wing *160* so that when the lip *180* is urged into contact with the spacer *120*, the second wing *160* has the desired angle relative to the spacer *120*. As discussed above, there are various ways that the second wing *160* is secured to the spacer *120*. **Figure 15A** depicts a top view of one such implant *600* placed between the spinous processes of adjacent cervical vertebrae. **Figure 16** is a top view illustrating two layers of distracting implants *600* with flared wings.

[0049] **FIG. 17** illustrates another embodiment *700* that uses "stops" or "keeps" *710*, which are rings of flexible biocompatible material, positioned around the spinous processes of adjacent cervical vertebrae and located posteriorly to the implant. The keeps *710* prevent backward displacement of the implants. The keeps generally include a ring *710* which has a slit *720* that goes completely through the ring. The keeps *710* can be somewhat sprung apart, so that the keep *710* can be fit over the end of the spinous process and then allowed to spring back together in order to hold a position on the spinous process. The

keep *710* can act as a block to the spacer *120* in order to prevent the implant from movement in a posterior direction.

[0050] It is to be understood that the implant and/or portions thereof can be fabricated from somewhat flexible and/or deflectable material. In these embodiments, the implant and/or portions thereof is made out of a polymer, more specifically, the polymer is a thermoplastic. Still more specifically, the polymer is a polyketone known as polyetheretherketone (PEEK). Still more specifically, the material is PEEK 450G, which is an unfilled PEEK approved for medical implantation available from Victrex of Lancashire, Great Britain. The Victrex website is located at www.matweb.com, or see Boedeker, at www.boedeker.com. Other sources of this material include Gharda located in Panoli, India, at www.ghardapolymers.com. The implant and/or portions thereof can be formed by extrusion, injection, compression molding and/or machining techniques. The material specified has appropriate physical and mechanical properties and is suitable for carrying and spreading the physical load between the spinous process. Further in this embodiment, the PEEK has the following additional approximate properties:

Property	Value
Density	1.3 g/cc
Rockwell M	99
Rockwell R	126
Tensile Strength	97 MPa
Modulus of Elasticity	3.5 GPa

Flexural Modulus 4.1 GPa

[0051] In an another preferred embodiment, the implant is comprised at least, in part of titanium or stainless steel, or other suitable implant material which may be radiopaque and, in part, of a radiolucent material that does not show up under x-ray or other type of imaging. In a preferred embodiment, the first wing ***130*** and second wing ***160*** and the shaft ***230*** are comprised of such a radiopaque material such as titanium and the spacer ***120*** and the distraction guide ***110*** are comprised of a radiolucent material such as, for example, PEEK or other radiolucent materials described herein. In an embodiment which includes the first wing ***130***, with the spacer ***120*** and the distraction guide ***110***, under imaging, the implant looks like a "T". In an embodiment which includes both a first and a second wing, the spacer and the tissue expander, under imaging, the implant looks like an "H". This embodiment allows the doctor to have a clearer view of the spine under imaging without the implant interfering as much with the view of the bone structure. Alternatively, the entire implant can be comprised of titanium or stainless steel.

[0052] It should be noted that the material selected may also be filled. For example, other grades of PEEK are also available and contemplated, such as 30% glass-filled or 30% carbon-filled, provided such materials are cleared for use in implantable devices by the FDA, or other regulatory body. Glass-filled PEEK reduces the expansion rate and increases the flexural modulus of PEEK relative to that which is unfilled. The resulting product is known to be ideal for improved strength, stiffness, or stability. Carbon-filled PEEK is known to enhance the compressive strength and stiffness of PEEK and lower its expansion rate. Carbon-filled PEEK offers wear resistance and load carrying capability.

[0053] In this embodiment, as described above, the implant is manufactured from PEEK, available from Victrex. As will be appreciated, other suitable similarly biocompatible thermoplastic or thermoplastic polycondensate materials that resist fatigue, have good memory, are flexible, and/or deflectable, have very low moisture absorption, and good wear and/or abrasion resistance, can be used without departing from the scope of the invention. The spacer can also be comprised of polyetherketoneketone (PEKK).

[0054] Other material that can be used include polyetherketone (PEK), polyetherketoneetherketoneketone (PEKEKK), and polyetheretherketoneketone (PEEKK), and generally a polyaryletheretherketone. Further, other polyketones can be used as well as other thermoplastics.

[0055] Reference to appropriate polymers that can be used in the implant can be made to the following documents, all of which are incorporated herein by reference. These documents include: PCT Publication WO 02/02158 A1, dated January 10, 2002, entitled "Bio-Compatible Polymeric Materials;" PCT Publication WO 02/00275 A1, dated January 3, 2002, entitled "Bio-Compatible Polymeric Materials;" and, PCT Publication WO 02/00270 A1, dated January 3, 2002, entitled "Bio-Compatible Polymeric Materials."

[0056] Other materials such as Bionate®, polycarbonate urethane, available from the Polymer Technology Group, Berkeley, California, may also be appropriate because of the good oxidative stability, biocompatibility, mechanical strength and abrasion resistance. Other thermoplastic materials and other high molecular weight polymers can be used.

[0057] A minimally invasive surgical method for implanting the cervical distraction device in the cervical spine is disclosed and taught herein. In this method, **Fig. 18**, preferably a guide wire ***880*** is

inserted through a placement network ***890*** into the neck of the implant recipient. The guide wire ***880*** is used to locate where the implant is to be placed relative to the cervical spine, including the spinous processes. Once the guide wire ***880*** is positioned with the aid of imaging techniques, an incision is made on the side of the neck about so that the first unit of the embodiment of the invention, which includes the distraction guide ***110***, the spacer ***120***, and the first wing ***130*** can be positioned in the neck thorough an incision and along a line that is about perpendicular to the guide wire ***880*** and directed at the end of the guide wire. The first unit is so inserted into the neck of the patient. Preferably during insertion, the distraction end pokes through or separates the tissue without severing the tissue. Next, the second wing ***160*** is inserted along a line that is generally colinear with the line over which the first unit is inserted but from the opposite side of the neck. The anatomy of the neck is such that it is most convenient and minimally invasive to enter the neck from the side with respect to the first unit and the second wing ***160***. The second wing ***160*** is mated to the first unit and, in this particular embodiment, the second wing ***160*** is snapped into engagement with the first unit. In an alternative embodiment, the second wing ***160*** is attached to the first unit by the use of a fastener, and in particular by a screw ***450***. The screw ***450*** is positioned using a screw driving mechanism that is directed along a posterior to anterior line somewhat parallel to the guide wire ***880***. This posterior to anterior line aids the physician in viewing and securing the second wing ***160*** to the first unit.

[0058] It is to be understood that the various features of the various embodiments can be combined with other embodiments of the invention and be within the spirit and scope of the invention. Thus, for example only, the embodiment of **Fig. 1** can have truncated wings as depicted in other

embodiments.

INDUSTRIAL APPLICABILITY

[0059] The above establishes that the present invention can be used to relieve pain associated with the cervical spine. The present invention is minimally invasive and can be used on an outpatient basis.

[0060] Additional aspects, objects and advantages of the invention can be obtained through a review of the appended claims and figures.

[0061] It is to be understood that other embodiments can be fabricated and come within the spirit and scope of the claims.

[0062] The foregoing description of preferred embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to one of the ordinary skill in the relevant arts. The embodiments were chosen and described in order to best explain the principles of the invention and its partial application, thereby enabling others skilled in the art to understand the invention for various embodiments and with various modifications that are suited to the particular use contemplated. It is intended that the scopes of the invention are defined by the claims and their equivalence.